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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,953	09/10/2003	Alexander Karl Huwig	20959/2140 (P 63469)	3518

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09/20/2007

EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,953	HUWIG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 June 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-10,13 and 21-26 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,11,12,14-20 and 27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 6/27/07. Claims 1, 2 and 4-27 are pending; claim 3 has been canceled; claims 5-10, 13 and 21-26 are withdrawn from consideration in the office action of 2/27/07 and as acknowledged by applicant in the remarks filed 6/27/07; claims 1, 2, 4, 11, 12, 14, 15-20 and 27 are examined.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 11, 12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Prencipe et al. (US 5,300,283) or

Prencipe discloses dentifrice composition that comprises polymer, sulfonic or phosphonic acid (column 4, lines 22-25, 31, 48-55; column 5, lines 39-43; column 6, lines 43-47); fluoride (column 2, line 6; column 9, lines 20-38) and the pH of the dentifrice composition is at about 4 to about 9 (column 2, lines 17 and 18); humectants such as polyethylene glycol , glycerin or sorbitol (column 8, lines 20-25) meeting claim 12; and abrasive or polishing material (column 8, lines 30-49). The lower end of the disclosed pH at 4 meets the upper end of the claimed pH at 4

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of claim 1; the fluoride meets claim 14; the sulfonic or phosphonic acid meets the acid requirement of claims 1, 4 and 11. Prencipe further discloses that other thickening agents may be included in the dentifrice composition and thickening agents such as xanthan gum, sodium carboxymethyl cellulose, polyvinylpyrrolidone, hydroxypropyl methylcellulose, alginates, locust bean gum and tamarind (column 9, lines 60-65; column 10, lines 16-19). “Protein and calcium-precipitating properties” is the property of the acid. MPEP 2112.01 [R-3] states “when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent.” In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). And “when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

3. Claims 1 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Pashley et al. (WO 9952498).

Pashley discloses method of desensitizing dentin by applying a composition, which is at pH of 4.0 and containing oxalic acid and hydroxyethyl cellulose (page 9, lines 3-5). The oxalic acid meets the requirements for acid in claim 1 and the hydroxyethyl cellulose meets the requirements for polymer in claim 1. MPEP 2112.01 [R-3] states “when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent.” In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). And “when the PTO shows a sound basis for believing that the products of the applicant and the

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prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

4. Claims 1, 2, 11, 12, 14-16, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Asano et al. (US 4,568,540).

Asano describes dentifrice composition containing fluoride ion from potassium or sodium fluoride at 0.0025 to 4% meeting claims 14 and 15, zinc ions, polyethylene glycol meeting claims 1 and 12, hydroxyethyl cellulose meeting the film forming polymer of claims 1 and 16, silica abrasive, xanthan gum or carrageenan at 0.2 to 5% meeting claims 1 and 12, humectants, succinic acid or gluconic acid or maleic acid or fumaric acid as buffering agents meet the acid of claims 1 and 11; 0.01 to 2% flavoring agent/sweetening meeting claim 19; ethanol/water solvent meeting claim 20; Asano specifically teaches that the pH of the composition should be maintained at acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). Claim 2 recites the properties of the acid and the presence of citric acid meets claims 1, 2 and 11. MPEP 2112.01 [R-3] states “when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent.” In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). And “when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 4, 11-20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540).

Hughes discloses liquid dentrifrice and mouthwash compositions that comprise one or more of oral composition components that are selected from abrasives, binders such as xanthan gum and carboxymethylcellulose at 0.1-5%, humectants, surfactants, fluoride ion sources, anticalculus agents and sweeteners and additionally comprises dimethicone copolyol selected from alkyl- and alkoxy-dimethicone copolyols (abstract; column 5, lines 30-35, 52-65); may also include lipophilic flavorants and lipophilic antimicrobial compounds (column 4, lines 29-62). Silica gels or xerogels (column 6, line 10) or calcium carbonate (column 6, lines 22 and 23) are

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abrasive agents. The composition of Hughes may also contain surfactants (column 6, lines 34-48), soluble fluoride ions such as sodium fluoride, stannous fluoride (column 6, lines 49-55), anti-calculus agents, of which specific example is zinc compounds (column 6, line 59 to column 7 line 22), sweetening and flavoring agents at 0.005 to about 2% and humectants (column 7, lines 23-26, 43), bleaching agent (column 7, line 52 to column 8, line 45), optional agents such as dyes/colorant, pH adjusting agents, plant extracts and desensitizing agents such as potassium nitrate, and mixtures thereof (column 7, lines 27-41), and effervescent agents such as carbonate that are effective under acidic conditions and mixed with organic acids such as citric acid, malic acid, succinic acid and gluconic acid (column 8, lines 13-23). The composition may also contain polyethylene glycols (column 10, lines 60 and 61) and phosphonic acid chelating agents at 0.1-1% (column 12, line 16); and the composition contains from about 0-60% or 5-30% ethanol when it is a mouthwash (column 7, line 45) meeting claim 20. The xanthan gum and polyethylene glycol meet the limitation of polymer in claims 1 and 12. The presence of phosphonic acid, citric acid meets the acid requirements of claims 1, 4 and 11. The fluoride ions meet the requirements of claim 14; potassium nitrate is a source of potassium ion meeting claim 15; carboxymethylcellulose meets the film-forming agent of claim 16; the sweetening agent at 0.005 to about 2% meets claim 19. Applying the composition containing desensitizing agent meets claim 27 and the composition of Hughes meets claim 18. The solubility of the acid recited in claim 2 is a property of the acid so that the acid of Hughes would have those properties and thus meet claim 2. Regarding claim 17, one film-forming agent may replace another without negatively affecting the composition . In this hydroxypropyl cellulose could be

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substituted for carboxymethyl cellulose with the expectation that the composition would be effective as a dentrifice.

Hughes discloses the claimed composition as described above. The difference between the Hughes composition and the claimed composition is that while Hughes teaches that the composition can be acidic, Hughes does not specifically teach a pH of from 1-4. However, Asano describes dentrifice composition containing fluoride ion from potassium of sodium fluoride at 0.0025 to 4%, zinc ions, polyethylene glycol, hydroxyl ethyl cellulose, silica abrasive, xanthan gum or carrageenan at 0.2 to 5%, humectants, succinic acid or gluconic acid or maleic acid or fumaric acid as buffering agents; 0.01 to 2% flavoring agent/sweetening; ethanol/water solvent; Asano specifically teaches that the pH of the composition should be maintained at acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). When Hughes in view of Asano are taken together, the ordinary skilled artisan would have been motivated to maintain the pH of the composition at acidic pH of from 3.5 to 6 with the expectation of maintaining the fluoride and zinc ions in solution.

8. Claims 1, 2, 4, 11, 12, 14-20 and 27are rejected under 35 U.S.C. 103(a) as being unpatentable over Norfleet et al. (US 5,352,439) in view of Asano et al. (US 4,568,540) and further in view of Patell (US 5,750,145).

Norfleet discloses oral composition, "such as a toothpaste," the composition comprises polyphosphate anti-tartar agent, synthetic anionic polymeric polycarboxylate or equivalent,

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fluoride, desensitizing proportion of pain inhibiting potassium salt, detergent or surfactant, sweetener and anti-calculus agent (abstract; column 1, lines 54-66; column 2, line 60 to column 3, line 11). The anti-calculus agents such phosphono compounds, which include phosphonic acids or derivatives, may be included in the composition in place of the anti-tartar polyphosphate (abstract; column 2, line 8-24; column 4, lines 24-38). The phosphates or phosphonic acid meets the acid in the composition defined by claims 2-4 and 11. The potassium salts disclosed release potassium ions into the toothpaste and into the mouth and into the teeth (column 2, line 65 to column 3, line 12), which meets claim 15. The composition further contains mixture of several humectants such as glycerol, sorbitol and polyethylene glycol (column 5, lines 27-33) and the polyethylene glycol, though referred to as humectant, is still polyethylene glycol, meeting the limitation of claim 12. The composition also contains bodying agent, gelling agent or thickener such as carrageenan (Irish moss), xanthan gum and sodium carboxymethyl cellulose, which are preferred, and also gum tragacanth, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose and hydroxyethyl cellulose (column 5, lines 22, 39-48). The agents used as gelling or thickening agents are film-forming agents and thus would inherently act as film forming agents meeting claim 16. Norfleet's mouthwash composition contains the components listed above and in addition contains base or solvent system of 20% ethanol in water (column 14, lines 18-23) meeting claim 20 and the solvent of claim 18. Fluoride is present at about 0.05% or 0.08% in the mouthwash (column 14, lines 25-27), b) the thickener is present at a range of 0.2-5% (column 9, lines 18-25), c) polyethylene glycol is present at 1-10% (column 9, lines 14 and 15) and specifically in combination with other humectants is present at about 3% (column 9, lines 16

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and 17), d) the fluoride is present at 100-2,300 ppm (0.01-0.23%) (column 8, lines 46-64), e) potassium ions present at 2-10% (column 8, lines 30-39; column 15, lines 2 and 3), f) phosphonic acid/derivative is present at 0.2% to 5% (column 14, line 67 to column 15, line 2), this composition meets claim 18. Flavors such as peppermint and spearmint are present in the composition (column 7, lines 13, 14 and 51; column 9, line 41) and the flavor is present at 0.5% to 2% (column 9, lines 41-45), which meets claim 19. The method of claim 27 applies the composition of claim 1 to a tooth. Norfleet discloses that the composition is desensitizing and toothpaste is applied to the tooth; Norfleet specifically discloses that potassium ion in the toothpaste "aids in desensitizing the teeth" (column 2, lines 17-20) and teaches a process for desensitizing sensitive teeth by applying the disclosed composition (claim 14). Thus, Norfleet meets claim 27.

Protein precipitating properties of the acid as recited in claim 1 is the properties of the acid and thus is met by the acid of the prior art. Claim 2 also recites the properties of the composition. Since the composition of Norfleet is the same as the claimed composition 1, it flows that the composition of Norfleet would have the same properties. MPEP 2112.01 [R-3] states "when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Norfleet discloses the claimed composition in which hydroxypropyl methyl cellulose and sodium carboxy methyl cellulose are present in the composition as thickening agents; although, film-forming agent represent a characteristic or intended use of the polymer, the thickening agents are also film-forming agents. Norfleet teaches that the composition should be maintained

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at a pH of from 6 to 8. The composition of Norfleet does not contain the specific polymer, hydroxypropyl cellulose, of claim 17. However, it is known in the art that hydroxypropylcellulose, hydroxypropyl methyl cellulose and sodium carboxy methyl cellulose all have the characteristic of film-forming or are film forming agents as disclosed by Patell in column 3, lines 53-57. Therefore, one film-forming agent can be used in place of the other with the expectation that the composition containing these agents form a film upon application. Furthermore, Asano describes dentifrice composition containing fluoride ion from potassium of sodium fluoride at 0.0025 to 4%, zinc ions, polyethylene glycol, hydroxyl ethyl cellulose, silica abrasive, xanthan gum or carrageenan at 0.2 to 5%, humectants, succinic acid or gluconic acid or maleic acid or fumaric acid as buffering agents; 0.01 to 2% flavoring agent/sweetening; ethanol/water solvent; Asano specifically teaches that the pH of the composition should be maintained at acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). When Norfleet in view of Asano and further in view of Patel are taken together, the ordinary skilled artisan would have been motivated to maintain the pH of the composition at acidic pH of from 3.5 to 6 and to use hydroxypropyl cellulose as the film forming agent with the expectation of maintaining the fluoride ions in a state that would prevent the precipitation of the fluoride in order to make the fluoride ions available for absorption.

And "when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

9. Applicant's arguments filed 6/27/07 as they relate to the present rejections immediately above have been fully considered but they are not persuasive.

Applicant argues that Norfleet teaches a composition whose pH is from 6 to 8 and more preferably from 6.5 to 7.5 while the claimed composition as now amended is at a pH of from 1 to 4 and that Patel does not make up for this deficiency by adjusting the pH of the Norfleet composition to form 1 to 4.

Response:

The examiner agrees with applicant that Norfleet suggests that the pH should be from 6 to 8 or from 6.5 to 7.5. A pH of 6 is however acidic. However, Asano is relied upon for suggesting that compositions containing fluoride ions should be maintained at acidic pH of from 3.5 to 6 in order to make available the fluoride ions for absorption since at basic pH, the fluoride ions precipitate. It may be noted that the lower pH limit of Norfleet is acidic at 6. Patell is relied upon for teaching that hydroxypropyl cellulose and carboxymethyl cellulose are all film forming polymers and is not relied upon for teaching pH of fluoride containing compositions.

Status Identifiers:

It is brought to applicant's attention that the withdrawn claims do not have the proper status identifiers. Applicant is thus reminded that, the future claims submitted should have the proper status identifiers. MPEP 714 [R-5] II under Manner of Making Amendments under 37 CFR 1.121.

No claim is allowed.

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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